IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

AMY DORAN, et al.,	:	
Plaintiffs,	:	**CIVIL ACTION**
v.	:	
MYLAN INC., et al.,	:	**No. 10-6539**
Defendants.	:	
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COLLEN GRIGSBY, et al.,	:	
Plaintiffs,	:	**CIVIL ACTION**
v.	:	
MYLAN INC., et al.,	:	**No. 10-6742**
Defendants.	:	
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MARILYN APPLE, et al.,	:	
Plaintiffs,	:	**CIVIL ACTION**
v.	:	
MYLAN INC., et al.,	:	**No. 10-6788**
Defendants.	:	
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TERRY REESE, et al.,	:	
Plaintiffs,	:	**CIVIL ACTION**
v.	:	
MYLAN INC., et al.,	:	**No. 10-6713**
Defendants.	:	
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CHRISTOPHER TISCH, et al.,	:	
Plaintiffs,	:	**CIVIL ACTION**
v.	:	
MYLAN INC., et al.,	:	**No. 10-6858**
Defendants.	:	

MEMORANDUM

Schiller, J. **January 19, 2010**

These cases arise from allegedly fatal defects in pharmaceutical patches used to treat chronic pain. Plaintiffs originally brought five separate wrongful death actions in the Philadelphia County Court of Common Pleas. Defendants removed these cases despite the presence of a Pennsylvania co-defendant, Mylan, Inc. They argue that Plaintiffs fraudulently joined Mylan to defeat diversity

jurisdiction. Plaintiffs' motions to remand are consolidated before this Court and are ripe for disposition. The Court will grant these motions for the reasons stated below.

I. BACKGROUND

Plaintiffs are proceeding on behalf of five individuals who died while using pain-treatment patches: David Doran, Kelley Reese, Martin Lalka, Stephen Apple, and Christopher Tisch (collectively, "Decedents").[1] In each case, the Decedent's patch was from a line of generic pharmaceutical products known as the Mylan Fentanyl Transdermal System ("MFTS"). (Defs.' Opp'n to Pls.' Mot. to Remand [Mylan Opp'n] 2-3.) Plaintiffs allege that due to its faulty design, the MFTS patch delivered a fatal dose of fentanyl to Decedents. (*See, e.g.*, Compl. of Amy Doran, et al. [Doran Compl.] ¶ 101.)

Fentanyl is a potent painkiller. (*Id*. ¶ 6.) Defendants designed the MFTS patch, which is a generic alternative to Duragesic, to release controlled amounts of fentanyl through the patient's skin in accordance with the dosage prescribed by the patient's physician. (*Id*. ¶¶ 24, 60-61; Mot. to Remand Ex. 1 [SEC Form 10-K of Mylan, Inc. for 2009] 6.) Plaintiffs allege that Defendants' failure to incorporate a "rate control membrane" in the MFTS patch's design resulted in Decedents receiving fatal overdoses of fentanyl. (*See* Doran Compl. ¶ 80.)

Plaintiffs' Complaints describe nine causes of action, including negligence in advertising, promoting and labeling the MFTS patch, and negligent failure to warn based on Defendants' failure to apprise the U.S. Food and Drug Administration ("FDA") and the public of the risk the patch

[1] The allegations in these five actions are essentially the same, outlining tort claims arising from use of Defendants' fentanyl patches. (*See* Defs.' Opp'n to Pls.' Mot. to Remand 4.)

posed. (*Id*. ¶¶ 54, 70.) The Complaints generally do not differentiate between Mylan, Inc. ("Mylan"), Mylan Pharmaceuticals, Inc. ("MPI") and Mylan Technologies, Inc. ("MTI"). All five Complaints allege claims against these three Defendants.

Mylan is a Pennsylvania corporation with its principal place of business in Pennsylvania. MPI is based and incorporated in West Virginia, while MTI is incorporated in West Virginia and has its principal place of business in Vermont. (Mylan Opp'n 4.) Defendants contend that Mylan did not design, manufacture, market or distribute the fentanyl patches at issue. (*Id*. at 2.) Rather, Mylan's two wholly-owned subsidiaries, MTI and MPI, manufactured and distributed the MFTS patches. (*Id*. at 4.) Mylan, according to Defendants, is merely a holding company whose involvement with the MFTS patch was limited to providing "administrative support and regulatory assistance" to its subsidiaries. (*Id*. at 8.)

Plaintiffs assert that this support and assistance constitutes tortious conduct which renders Mylan liable on Plaintiffs' failure to warn claims. (Mot. to Remand 8-12.) To support this position, Plaintiffs provided deposition testimony by a former Mylan employee, Frank Sisto**,** taken in a case pending in New Jersey. (*Id*. at 8; Mot. to Remand Ex. 2 [Sept. 16, 2010 Deposition of Frank Sisto] ("Sisto Dep.").) Sisto served as Mylan's global head of regulatory affairs until his retirement in March 2009. (Sisto Dep. 5-6.) He testified that he coordinated regulatory affairs for the Mylan entities, acting as the companies' primary contact with the FDA. (*Id*. at 7-8.) Sisto was also involved with the labeling of the MFTS patch. (*Id*. at 14-15.) Though he testified that he had "very, very little" to do with "actually putting that labeling together," Sisto confirmed that he reviewed information for a labeling supplement Mylan submitted to the FDA regarding the MFTS patch. (*Id*.)

Plaintiffs submit that Mylan was responsible for the MFTS patch's label and for updating the

patch's product warnings. (Mot. to Remand 11.) Defendants dispute the extent to which Mylan or Sisto were involved with the MFTS patch project, but agree Sisto's testimony "indicates that Mylan Inc. provided assistance to [MTI] in maintaining regulatory compliance for the MFTS by maintaining and coordinating communications with . . . the Food and Drug Administration." (Mylan Opp'n 19-20.)

Plaintiffs' actions were consolidated before this Court for resolution of their motions to remand on December 14, 2010. Defendants filed a global opposition on January 7, 2011.

II. STANDARD OF REVIEW

A defendant seeking to invoke federal diversity jurisdiction may only remove a case to federal court if "none of the parties in interest properly joined and served as defendants is a citizen of the State in which the action is brought." 28 U.S.C. § 1441(b). Nevertheless, district courts may disregard a defendant's citizenship for jurisdictional purposes upon a showing of fraudulent joinder. *In re Briscoe*, 448 F.3d 201, 216 (3d Cir. 2006). Joinder is fraudulent if either (1) a reasonable basis in fact or colorable ground supporting the claim, or (2) a good-faith intention to prosecute the action against the defendant in question is lacking. *Id*. (citing *Abels v. State Farm Fire & Cas. Co.*, 770 F.2d 26, 32 (3d Cir. 1985)). The removing defendant bears the burden of demonstrating that jurisdiction is appropriate. *See Wilson v. Republic Iron & Steel Co.*, 257 U.S. 92, 97 (1921); *Boyer v. Snap-on Tools Corp.*, 93 F.2d 108, 111 (3d Cir. 1990).

The Court will accept Plaintiffs' well-pleaded allegations as true and resolve "any uncertainties as to the state of controlling substantive law in favor of the plaintiff." *Briscoe*, 448 F.3d at 217 (quoting *Batoff v. State Farm Ins. Co.*, 977 F.2d 848, 851-52 (3d Cir. 1992)). The Court

may look beyond the pleadings to determine whether joinder was fraudulent. *See id*. at 219. However, the Court will not "step from a threshold jurisdictional issue into a decision on the merits." *See Weaver v. Conrail, Inc.*, Civ. A. No. 09-5592, 2010 WL 2773382, at *6 (E.D. Pa. July 13, 2010) (citing *Briscoe*, 448 F.3d at 218).

III. DISCUSSION

Defendants assert that Plaintiffs have failed to advance viable claims against Mylan and have not pursued their claims against the company in good faith.

A. Viability of Plaintiffs' Claims Against Mylan, Inc.

Defendants cannot establish fraudulent joinder based on defects in Plaintiffs' claims if a claim against Mylan is "colorable," i.e., not "wholly insubstantial and frivolous." *See Batoff*, 977 F.2d at 852 (internal quotation marks omitted). A claim is thus "colorable" if there is "any possibility that a state court would entertain the cause."[2] *Uon v. Tanabe Int'l Co.,* Civ. A. No. 10-5185, 2010 WL 4946681, at *2 (E.D. Pa. Dec. 3, 2010) (quoting *Briscoe*, 448 F.3d at 219). To establish fraudulent joinder, Defendants must therefore show that Plaintiffs' bid for recovery from Mylan is not only weak, but practically "a clear legal impossibility." *West v. Marriot Hotel Servs., Inc.*, Civ. A. No. 10-4130, 2010 WL 4343540, at *3 (E.D. Pa. Nov. 2, 2010); *see also In re Avandia Mktg., Sales Practices and Prods. Liab. Litig.*, 624 F. Supp. 2d 396, 418 (E.D. Pa. 2009) (noting that courts must not conduct a "summary judgment type inquiry" into fraudulent joinder, but rather

[2] The parties agree that Pennsylvania law governs these state law claims for the purposes of the present inquiry. (Mylan Opp'n 8.) The Court will thus apply Pennsylvania law to Plaintiffs' tort claims. *See Moorco Int'l, Inc. v. Elsag Bailey Process Automation, N.V.*, 881 F. Supp. 1000, 1004 (E.D. Pa. 1995).

examine "whether the facts pleaded are impossible or fatally inconsistent.").

Defendants have not met this burden. Plaintiffs have plead a facially viable negligence claim against Mylan based on its role in managing regulatory compliance for the MFTS patch. Mylan's independent actions on behalf of its subsidiaries constitute a reasonable basis for colorable claims against Mylan without piercing the parent company's corporate veil.

1. Pharmaceutical failure to warn claims

Pennsylvania courts apply a negligence standard to failure to warn claims involving drug manufacturers, looking to the Restatement (Second) of Torts § 388. *See Lance v. Wyeth*, 4 A.3d 160, 165-65 (Pa. Super. Ct. 2010) (citing *Hahn v. Richter*, 673 A.2d 888, 890-91 (Pa. 1996)). Pennsylvania has also adopted the "learned intermediary doctrine" in cases involving a failure to warn of risks associated with prescription drugs. *Cochran v.Wyeth, Inc.*, 3 A.3d 673, 676 (Pa. Super. Ct. 2010). A manufacturer will thus be liable for failing to exercise reasonable care to inform a physician of facts which make the drug likely to be dangerous. *Id*. (citing *Taurino v. Ellen*, 579 A.2d 925, 927 (Pa. Super. Ct. 1990)). To bring such a claim to a jury, the evidence must establish a "reasonable likelihood that an adequate warning would have prevented the plaintiff from receiving the drug." *Id*. (citing *Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1155 (Pa. Super. Ct. 1996)).

Plaintiffs allege Defendants failed to inform "the FDA, the prescribing medical professionals and the public" of the "true and, known to the Defendants, deadly risk posed by the [MFTS] Patch." (Doran Compl. ¶¶ 69-70.) Plaintiffs also plead that Defendants' inadequate warnings regarding the risk of fentanyl poisoning caused the Decedents' deaths, as their doctors would not otherwise have prescribed them Defendants' patch. (*Id*. ¶¶ 73-75.) Taking Plaintiffs' allegations as true, the Court

concludes that they have plead a viable failure to warn claim against the MFTS patch's manufacturer, MTI. As Plaintiffs provide evidence that MTI effectively outsourced its labeling and regulatory responsibilities to Mylan, Mylan's liability for this failure to warn follows from MTI's own liability.

2. Mylan's role in labeling and regulatory compliance of the MFTS Patch

A corporation may be liable for its own negligence when it chooses to perform duties which its subsidiary owes to third parties. *See Kirschbaum v. WRGSB Assocs.,* 243 F.3d 145, 155 (3d Cir. 2001) (discussing Restatement (Second) of Torts § 324A). Defendants argue at length that the Court should not consider Mylan, MTI and MPI to be alter egos, contending that each Defendant has maintained a separate corporate identity sufficient to resist Plaintiffs' attempts to pierce the corporate veil. (*See* Mylan Opp'n 12-14.) Assuming Defendants carried this point, the Court nevertheless concludes that Mylan's role in interfacing with the FDA constituted performance of a duty owed to third parties which may trigger liability under § 324A.

Pharmaceutical manufacturers have a continuing obligation to investigate and report adverse events associated with products after obtaining FDA approval. *Wyeth v. Levine*, 129 S.Ct. 1187, 1219 (2009); *see also* 21 C.F.R. § 314.80. Defendants concede that Mylan maintained and coordinated communications with the FDA on its subsidiaries' behalf. (See Mylan Opp'n 19-20.) Specifically, Mylan's regulatory affairs office served as the "primary" point of contact between the FDA and the MFTS patch's manufacturer, MTI. (*See* Sisto Dep. 8, 35.) The parent company's regulatory affairs department was also responsible for collecting product information and submitting it to the FDA. (*Id*. at 7-8.) In fact, Mylan employee Frank Sisto personally met with the FDA in September of 2005 to discuss the MFTS patches. (*Id*. at 20.) When the FDA wanted information

regarding a death linked to an MFTS patch, the agency contacted Sisto's office "to try to get some information on that, that we had indicated that we had not, you know, received that particular [report], but then, you know, we looked into it from there." (Sisto Dep. 22-23.)

Defendants provide a letter from the FDA's Office of Generic Drugs to William Brochu, an MTI employee based in Vermont, suggesting that the FDA may have dealt with MTI directly. (Mylan Opp'n Ex. B [Jan. 28, 2005 Letter from Gary Buehler to William Brochu].) However, the existence of subordinate regulatory and compliance departments within the subsidiary companies is not inconsistent with Plaintiffs' position that Mylan retained ultimate responsibility for the companies' relationship with the FDA. Indeed, Sisto specifically testified that Brochu, the MTI official addressed in Defendants' letter, was Sisto's subordinate. (Sisto Dep. 34.) This evidence that Mylan managed and coordinated MTI's regulatory compliance supports Plaintiffs' claims against it. *Cf. Hutton v. Teva Neurosci., Inc.*, Civ. A. No. 08-1010, 2008 WL 4862733, at *2 (E.D. Mo. Nov. 7, 2008) (finding that plaintiff asserted colorable claim for failure to warn against resident defendant which "house[d] a business unit responsible for reporting to the Federal Drug Administration adverse reactions to drugs manufactured by" its sister corporation).

It is also uncontested that Sisto was involved with the labelling of the MFTS patch in his capacity as global head of regulatory affairs — Defendants dispute only the extent of Sisto's involvement. (*See* Mylan Opp'n 19.) Taken together, the pleadings and evidence demonstrate that Plaintiffs have a colorable claim that Mylan was negligent in rendering regulatory and compliance services on behalf of its subsidiaries and thus may be liable in keeping with § 324A. *Cf. Ponca Tribe of Indians of Okla. v. Cont'l Carbon Co.*, Civ. A. No. 05-445, 2008 WL 5205679, at *2 (W.D. Okla. Dec. 11, 2008).

B. Plaintiffs' Good Faith

Defendants argue that Plaintiffs do not in good faith intend to pursue their claims against Mylan. In particular, Defendants note that one Plaintiff named only MPI in an earlier action in a West Virginia state court. (Mylan Opp'n 22.) Defendants' good faith argument otherwise relies on a summary judgment ruling from another federal district court, in which Plaintiffs' attorneys allegedly "half-heartedly" pursued unsuccessful claims against the parent company. (*Id*. at 23.) The Court finds that Defendants have nevertheless failed to overcome Plaintiffs' representations through counsel that they have a real intention to prosecute their claims against Mylan in good faith. *Cf. Kuresa-Boon v. Mylan Pharms., Inc.*, Civ. A. No. 08-1452, 2008 WL 3833220, at *2 (E.D. Pa. Aug. 14, 2008). As Plaintiffs have set forth viable claims against Mylan itself and appear to pursue these claims in good faith, the Court will not disregard Mylan's citizenship.

IV. CONCLUSION

Defendants have failed to establish that Plaintiffs fraudulently joined Mylan. The Court will thus grant Plaintiffs' motions to remand. An Order consistent with this Memorandum will be docketed separately.